

**REMARKS**

Entry of the foregoing, reexamination and reconsideration of the subject application, as amended, pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested in light of the remarks which follow.

As noted in the Office Action, claims 1-35 are pending. Applicants note with appreciation that claims 1-16 stand allowed. Claims 1, 17, 19, and 35 are amended herein and new claim 36 is added. Claims 2-7, 11-15, and 20 are cancelled herein without prejudice or disclaimer thereto. Basis for the amendments and new claims may be found throughout the specification and claims as-filed, and no new matter is presented by way of the present amendment. Applicants reserve the right to file at least one continuation application directed to any subject matter cancelled by way of the present amendment.

***Declaration Pursuant to 37 C.F.R. § 1.132***

Attached hereto is a Declaration pursuant to 37 C.F.R. § 1.132 by Robert Hesslink. The Declaration provides further clarification as to the mechanism of action of the presently claimed esterified fatty acids. The esterified fatty acids of the presently claimed invention are fatty acids esterified to cetyl alcohol. These esterified fatty acids (EFAs) have increased efficacy against diseases relating to inflammation. These properties are not present in other fatty acids. For example, EFAs act to inhibit mediators of inflammation and reduce the amount of arachidonic acid in cell membranes, also reducing eicosanoid production. It is the esterified fatty acids of the present compositions and formulations that provide the benefits in treatment.

Applicants have amended the claims herein to recite treatment of arthritis, periodontal disease, psoriasis, or a cardiovascular or heart disease. The Declaration of Robert Hesslink provides further support for the efficacy and mechanism of action of the claimed compositions and formulations for the treatment of these disease conditions. As discussed in the Declaration, studies have been performed showing the mechanism of action of the esterified fatty acids, and their ability to treat periodontal conditions and the agents that cause these conditions. Further, the effect of the fatty acids on inflammation is discussed. Applicants submit that the esterified fatty acids are effective in the

treatment of arthritis, periodontal disease, psoriasis, or a cardiovascular or heart disease.

***Rejections Under 35 U.S.C. §112, first paragraph***

Claims 17-35 stand rejected under 35 U.S.C. § 112, first paragraph as purportedly failing to comply with the enablement requirement. The Office asserts that while the specification is enabling for the treatment of arthritis, it is not enabling for prevention of disease. In the interest of expediting prosecution, and without acquiescing in the rejection, independent claims 17 and 35 are amended herein to recite treatment and to remove the recitation of prevention. Applicants request that this rejection be withdrawn.

**CONCLUSION**

It is respectfully submitted that all rejections have been overcome by the above amendments. Thus, Notice of Allowance is respectfully requested.

In the event that there are any questions relating to this Amendment or the application in general, it would be appreciated if the Examiner would contact the undersigned attorney by telephone at (703) 836-6620 so that prosecution of the application may be expedited.

Respectfully submitted,

BUCHANAN INGERSOLL PC  
(INCLUDING THE ATTORNEYS FROM BURNS DOANE SWECKER & MATHIS)



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By: \_\_\_\_\_

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